

DETAILED ACTION

Responsive to communications entered 4/23/2010. Claims 1-81 are pending.

Each of the restriction requirements mailed 4/4/2008 and 12/9/2009 are hereby **vacated** in favor of below.

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

When Claims Are Directed to Multiple Categories of Inventions:

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c)

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-45, 64,65 drawn to a method for the making a library of templated molecules.

Group II, claim(s) 46-50, drawn to a method for the manufacture of a library of templated molecules including a transfer step.

Group III, claim(s) 51,66-81 drawn to a library of templated molecules.

Group IV, claim(s) 52-63, drawn to a method of enriching templated molecules.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of groups I-IV appears to be related to a method of preparing a library of templated molecules, with steps outlined in claim 1.

However, the method set forth in claim 1 was known in the art at the time the invention was filed (Liu et al US Application 2003/0113738: see especially the abstract,

figure 3 and figure 18 center first two steps), therein the technical feature linking all the inventions of groups I-IV does not constitute a *special* technical feature as defined by PCT Rule 13.2, because it does not define a contribution over the prior art.

The invention set forth as group III, above requires materially different steps, such as DNA amplification which is not required in practicing the templating procedure, that is set forth as groups I and II above. The transfer protocol set forth as group II, above is not required for the enrichment procedure of invention IV or preparation of the templated molecules of invention I. The product of invention III may be prepared by other means, such as *in vivo* translation or by chemical synthesis. Therefore, inventions I, II and IV lack unity with one another as well as the product that is invention III.

Markush Group Member (Species) Election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Each **genus** identified below is indicated in **bold**. Applicant is requested to elect one species from within *each* genus of the elected invention.

From the library, applicant is required to elect single specific species of **template**, such as set forth in claim 1 (a) and paragraphs 0085-0087 of the present published application selected from the group consisting of: DNA, RNA, PNA and LNA. Currently, claims 1,2-16,24-34,38,43-45,64,65 are generic for invention I, claims 46-50 are generic

for invention II, claims 51,66-81 are generic for invention III, claims 52-63 are generic for invention IV.

From the library, applicant is required to elect single specific species of **molecule linked to building block** thereto such as set forth in claims 1(b), 51. While applicant is not required to elect a particular anticodon, the complete chemical connectivity of the molecule, linker and building block is to be specified as to atom and bond. Applicant is required to elect using a chemical drawing. Currently, claims 1,6,17-37,45,64,65 are generic for invention I, claims 46-50 are generic for invention II, claims 51,66-81 are generic for invention III, claims 52-63 are generic for invention IV.

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed sequences, the Markush group shall be regarded as being of similar nature when

(A) all alternatives have a common property or activity **and**

(B)(1) a common structure is preset, i.e., a significant structure is shared by all of the alternatives or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

The species listed above are considered to be each separate inventions for the following reasons:

The genus/genera set forth above include species which do not share a common core structure. Notably none of the templates and molecule-building blocks do not share a common chemical core across the claimed genus, thus not expected to have similar activity or properties. For example, unlike DNA, PNA and LNA, RNA templates are base labile; PNAs have a uncharged backbone unlike DNA or RNA. Unlike steroids, molecules such as chelates coordinate metals.

From the library, applicant is required to elect single specific species of **chemical connection**, such as set forth in claim 1(d) (e.g. amide). Currently, claims 1,2-5,39-40 are generic for invention I, claims 46-50 are generic for invention II, Claim 51 is generic for invention III, Claims 52-63 are generic for invention IV.

Each chemical connection does not share a common technical feature in that each requires materially different steps to perform (e.g. different reagents). For example, unlike amide bonds disulfide bonds are formed oxidatively.

Applicant is required to elect single specific species of **predetermined activity**, such as set forth in claim 52 (ii). Currently, claims 52,57-60,62 are generic for invention II.

Each activity does not share a common technical feature in that each requires materially different steps to perform, such as measuring the reaction kinetics associated with catalysis vs. the cytology associated for determining cell internalization.

Applicant is required to elect single specific species of **enrichment step**, such as set forth in claims 61. Currently, claims 52, 61 are generic for invention II.

Each enrichment method does not share a common technical feature in that each requires materially different steps to perform, such as electrophoresis does not require the centrifuge associated with centrifugation.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of

the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Miscellaneous Issues

If applicant again chooses to elect a Feuston analog as for the species of **molecule linked to building block**, a follow up interview from regarding the chemistry occurring in examples 4 and 5 and figure 30 of the disclosure is strongly suggested.

Unfortunately, applicant's representative, Iver Cooper will not be available again until 8/16/2010 and his assistant indicated he prefers handling his cases personally.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER M. GROSS whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571 272 0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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